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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,434	04/14/2000	CORNELIA BERGHOF	2727-100J	1917

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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	

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19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/485,434	Berghof et al
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 7, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 7, 10-12, 16-18, 20-22, 24-26, 28-43, and 48 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 16 and 48 is/are allowed.

6) ☒ Claim(s) 7, 10-12, 17, 18, 20-22, 24-26, and 28-43 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 11/7/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/485,434 is acceptable and a CPA has been established. An action on the CPA follows.

2. Currently, claims 7, 10-12,16-18, 20-22, 24-26, 28-43, and 48 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is Non-Final.

Specification

3. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-Reference to Related Applications.
© Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
(e) Background of the Invention.
1. Field of the Invention.
2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Claim Objections

4. Claims 10, 11, 22, 18, 20, 21, 29-31 33-35, 37-39, and 41-43 are objected to as being of improper dependent form because these claims fail the infringement test. See MPEP 608.01(n). The method of claims 18, 20, and 21 can be separately infringed from the method of kit of claim 48. The products of claims 37-38, and 41-42 can be separately infringed from the products of claims 36 and 40 respectively.

The products of claims 10 and 22 can be separately infringed from the products of claim 7 because claim 7 is drawn to a sequence that 'comprises at least 10 contiguous nucleotides of a sequence represented by SEQ ID NO 1, for example, which necessarily stipulates that at least 10 sequences of one of the SEQ ID NOS recited is present, whereas claim 10 adds the limitation that

'each sequence contains 10-250 nucleotides' which broadens the claim as it encompasses 10 contiguous nucleotides that don't have to be in SEQ ID NO 1, but can be on either side of SEQ ID NO 1. The same analysis holds for claims 22, 29, 30, 33, 34, 37, 38, 41, and 42.

Further, the products of claims 11, 31, 35, 39, and 43 do not necessarily further limit the claims from which they depend as the recitation of "complementary" has not been defined and could encompass sequences with only a certain degree of complementarity to SEQ ID NOS 1-10.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Written Description

5. Claims 7, 10-12, 22, 24-26, and 28-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to sets of nucleic acid molecules that comprise 10 contiguous nucleotides of a sequence 'represented by' SEQ ID NOS 1-9 or 10, or the complement of SEQ ID NOS 1-9 or 10 or to nucleic acid molecules "represented by' SEQ ID NOS 1-9 or 10 or the complement of SEQ ID NOS 1-9 or 10 wherein the set is used in nucleic acid hybridization or amplification to detect all representatives of Salmonella enterica subspecies

enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica. The claims further comprise nucleic acids which contain 10-250 or 15-30 nucleotides.

The specification discloses the sequences of SEQ ID NOS 1-10 and teaches that the sequences are identical or altered with respect to a specific region of a fragment of Salmonella typhimurium LT2 chromosome which is taught by Holmes et al in WO9500664 (the fragment is denoted as SEQ ID NO 1 in WO9500664). Holmes et al, however, do not teach the complete sequence of the LT2 chromosome or whether SEQ ID NO 1 is a sequence within a specific gene, or intervening sequence. Therefore, the recitation of "comprising" (which is considered 'open' language) in claims 7, 28, and 32, and the minimal length of "10 contiguous nucleotides", encompasses partial genomic sequences of undetermined length (not defined by the specification) as well as complete genes from any serotype of Salmonella which have not been taught or described by the specification. Further, the recitation of "represented" in claims 7, 28, 32, 36, and 40 encompasses sequences larger than the claimed SEQ ID NOS (the specification does not define the meaning of the term and therefore it has been broadly interpreted to encompass a larger sequence than the recited SEQ ID NO as such larger sequences could be considered to be "represented" by the smaller SEQ ID NOS) as well as variants of the claimed SEQ ID NOS. The disclosed structural features of SEQ ID NOS 1-10, however, do not represent a substantial portion of the claimed genomic sequences, genes, variants, or homologues. The claimed limitation that the sequences are used to detect all representatives of Salmonella enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica does not limit

the large genus of nucleic acids as the specification has not described any distinguishing characteristics of the undisclosed sequences which are encompassed by the claims that would allow the detection of all representatives of Salmonella enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica. It is noted that the claims also encompass the complete S. Typhimurium LT2 chromosome, but that such was not taught in either the specification or the art at the time the invention was filed. The sequence of the LT2 chromosome was first disclosed by McClelland et al (Nature, vol. 413, 2001, pp 852-856). Further, McClelland teaches that S. Bongori and S. Arizonae share 85% and 83% homology with coding sequences of the LT2 chromosome, illustrating that considerable variability exists between the different species. However the specification has not taught or described the identity of sequences which could additionally be used to detect the different Salmonella species recited in the claims, nor has the specification provided an alignment of the chromosomes of the different Salmonella species recited such that the skilled artisan would be able to determine which sequences could be used to detect all representatives of Salmonella enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica.

Isolated nucleic acids consisting of a sequence from the group consisting of SEQ ID NOS 1-9 and 10 and complements of such meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to and encompass full length genes, genomic sequences, variants and homologs, none of which meet the written description provision of 35

USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 1-10 and complements of such, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Enablement

6. Claims 7, 10-12, 22, 24-26, and 28-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid sequences consisting of SEQ ID NOS 1-10 and complements of such, does not reasonably provide enablement for a nucleic acid sequence which comprises at least 10 contiguous nucleotides of a sequence represented by SEQ ID NOS 1-9 or 10 or complements of such, or to a nucleic acid sequence represented by SEQ ID NOS 1-9 or 10, or complements of such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to sets of nucleic acid molecules that comprise 10 contiguous nucleotides of a sequence 'represented by' SEQ ID NOS 1-9 or 10, or the complement of SEQ ID NOS 1-9 or 10 or to nucleic acid molecules "represented by' SEQ ID NOS 1-9 or 10 or the complement of SEQ ID NOS 1-9 or 10 wherein the set is used in nucleic

acid hybridization or amplification to detect all representatives of Salmonella enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica. The claims further comprise nucleic acids which contain 10-250 or 15-30 nucleotides.

The specification discloses the sequences of SEQ ID NOS 1-10 and teaches that the sequences are identical or altered with respect to a specific region of a fragment of Salmonella typhimurium LT2 chromosome which is taught by Holmes et al in WO9500664 (the fragment is denoted as SEQ ID NO 1 in WO9500664). Holmes et al, however, do not teach the complete sequence of the LT2 chromosome or whether SEQ ID NO 1 is a sequence within a specific gene, or intervening sequence. Therefore, the recitation of "comprising" (which is considered 'open' language) in claims 7, 28, and 32, and the minimal length of "10 contiguous nucleotides", encompasses partial genomic sequences of undetermined length (not defined by the specification) as well as complete genes from any serotype of Salmonella which have not been taught or described by the specification. Further, the recitation of "represented" in claims 7, 28, 32, 36, and 40 encompasses sequences larger than the claimed SEQ ID NOS (the specification does not define the meaning of the term and therefore it has been broadly interpreted to encompass a larger sequence than the recited SEQ ID NO as such larger sequences could be considered to be "represented" by the smaller SEQ ID NOS) as well as variants and homologs of the recited SEQ ID NOS. The disclosed structural features of SEQ ID NOS 1-10, however, do not enable the skilled artisan to determine which additional sequences on either side or 'represented by' the disclosed sequences could be used to detect all representatives of Salmonella

enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica. Further, the specification does not provide any guidance (for example, nucleic acid sequences of disclosed Salmonella species, or in the form of an alignment) for the skilled artisan to be able to determine which additional sequences or sequences 'represented by' the recited SEQ ID NOS could be used for such detection. It is noted that the claims also encompass the complete S. Typhimurium LT2 chromosome, but that such was not taught in either the specification or the art at the time the invention was filed. The sequence of the LT2 chromosome was first disclosed by McClelland et al (Nature, vol. 413, 2001, pp 852-856). Further, McClelland teaches that S. Bongori and S. Arizonae share 85% and 83% homology with coding sequences of the LT2 chromosome, illustrating that considerable variability exists between the different species. However the specification has not taught or described the identity of sequences which could additionally be used to detect the different Salmonella species recited in the claims, nor has the specification provided an alignment of the chromosomes of the different Salmonella species recited such that the skilled artisan would be able to determine which sequences could be used to detect all representatives of Salmonella enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica. While Holmes teaches a partial alignment of a fragments of the LT2 chromosome and relevant fragments from different Salmonella species, this alignment does not include the regions of the sequences recited in the instant specification, nor does it include which relevant sequences from all of the recited Salmonella enterica subspecies: enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica.

With the exception of SEQ ID NOS: 1-10 and complements of such, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides regardless of the complexity or simplicity of the method of isolation. The skilled artisan would have to perform trial and error analysis, the results of which are unpredictable given the lack of disclosure in the specification or the art as to the identity of additional sequences, especially those of undetermined length or as large as 250 nucleotides, which could be used to detect all representatives of Salmonella enterica subspecies enterica, salamae, arizonae, diarizonae, houtenae, bongori, and indica, to determine if any nucleic acid sequence which comprises 10 contiguous nucleotides of a sequence 'represented' by SEQ ID NOS 1-9 or 10 or nucleic acid sequences which are 'represented by' SEQ ID NOS 1-9 or 10, would be encompassed by the claimed nucleic acids.

Indefinite

7. Claims 7, 10-12, 17-18, 20-22, 24-26, and 28-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 7, 28, 32, 36, and 40 are indefinite in the recitation of "represented" as it is unclear if this encompasses sequences which are larger than the recited SEQ ID NOS, sequences smaller than the recited SEQ ID NOS, or to sequences which can have variable nucleotides with regard to the recited SEQ ID NOS. The specification does not define this term, and therefore the metes and bounds of the claims are unclear.

B) Claims 10, 12, 22, 29, 30, 33, 34, 37, 38, 41, and 42 are indefinite in the recitation of "each sequence" or "the sequence" as this recitation lacks sufficient antecedent basis. It is unclear if the recitation of 'each sequence' or 'the sequence' is drawn to the full nucleic acid molecule in the set of claim 7 or to the region of the nucleic acid molecule which "comprises 10 contiguous nucleotides".

C) Claim 22 is indefinite as it is unclear if the claim is drawn to a set of nucleic acid molecules or to a single nucleic acid molecule (it is noted that the claim depends from claim 10 and that claim 10 is drawn to a set of nucleic acid molecules).

D) Claims 37, 38, 41, and 42 are indefinite as it is unclear how the minimum length of the sequence of claim 36 (or 40) seems to be 20 nucleotides, but the claims which depend therefrom have all the limitation of claim 36 (or 40) but are shorter claims 37, 38, 41, and 42 seem to indicate a minimum length of 10 or 15 nucleotides. In such instances, the dependent claims do not further limit the independent claims.

E) Claim 18 is indefinite as it is unclear which part of the kit of claim 48 is used in the method of claim 18.

F) Claim 21 lacks sufficient antecedent basis for the terms "the bacteria not to be detected", "the region" as neither recitation finds support in the claim or the claims from which it depends.

G) Claim 21 is grammatically incorrect in the recitation of "and representatives of a group of bacteria of the Salmonella genus are detected" which renders the claim indefinite as it is unclear if such recitation is an additional step in the method of claim 18.

I) Claims 11, 31, 35, 39, and 43 are indefinite in the recitation of "or has a complementary strand" as it is unclear if 'complementary' is meant as 'the complement' (that is, the full complement) or whether such encompasses a partial complement or a homologue.

J) Claim 17 is indefinite in the recitation of 'does not comprise any degenerate nucleic acid molecules" as it depends from claim 48, which does not recite the limitation of 'degenerate nucleic acid molecules' therefore, it is unclear how claim 17 further limits claim 48.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 7, 10-12, 18, 20-22, 24-26, and 28-43, are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes et al (WO 95/00664).

Firstly, it is noted that the intended use for the claims carries no patentable weight. Holmes teaches a sequence designated as SEQ ID NO 1, which is identical at positions 1336-1355 to SEQ ID NO 1 of the present invention. Therefore, the sequence of Holmes is 'represented' by SEQ ID NO 1 of the instant specification (with regard to claims 7, 28 and 36). It is further noted that the specification does not define the meaning of the term 'represented', therefore the term has been broadly interpreted to encompass a single base change. Accordingly, SEQ ID NO 1 of Holmes is 'represented' by SEQ ID NO 2 of the instant claims. The term 'represented' has also been broadly interpreted to encompass sequences that are in some way related to each other, ie: they can hybridize to a common sequence (with regard to claims 32 and 40). Accordingly, probe ST14 is represented by SEQ ID NOS 1 or SEQ ID NO 2 for example, of the instant claims as either sequence can hybridize to a sequence in common with probe ST14 (which is single stranded) of Holmes, that is, SEQ ID NO 1 taught by Holmes (with regard to claims 10 - 12, 22, 29-31, 33-35, 37-40, and 41-43). It is further noted that Holmes teaches on page 12, that the probes, ie ST14, were labeled with P^{32} (with regard to claims 24-26).

With regard to claims 18, 20, and 21, Holmes teaches that nucleic acid based methods for detection of a DNA or RNA from a target organism have proliferated and that the invention of Holmes is based on using certain fragments of the *Salmonella typhimurium* LT2 chromosome (or corresponding nucleic acid fragments having the same sequence of bases, including RNA, PNA, etc) as primers in PCR and other amplification systems, in particular certain fragments corresponding to regions of the genome which are highly conserved in *Salmonella* species (see

paragraph bridging pages 2 and 3). Holmes further teaches that fragments to conserved regions are useful in detecting and identifying *Salmonella* species generally, while fragments from less conserved regions are useful for identifying infections from different serotypes of *Salmonella* (see p. 3). Holmes teaches using 146 *Salmonella* strains (table 2) and 82 non *Salmonella Enterobacteriaceae* strains (table 3). Holmes further teaches that 8 oligonucleotide sequences were selected from the sequence and tested for their ability to discriminate between *Salmonella* and non *Salmonella* bacteria and teaches various results in the primer pairs ability to identify and distinguish *Salmonella* form non *Salmonella* bacteria and form different serotypes of *Salmonella* (see p. 14, 15, and table 1,2 and 3, examples 1 and 2). Holmes specifically teaches evaluation of a *Salmonella* specific PCR assay and the detection of *enterica, salamae, arizonae, diarizonae, houtenai, bongori,* and *indica* and teaches application of the general method in the detection of *Salmonella* in pork and beef (example 3). As the claims do not specifically state which part of the kit of claim 48 is being used, or how, the claims have been broadly interpreted to encompass using the substances for analytical detection purposes of claim 48, which Holmes teaches (see p. 19, where Holmes teaches using dig-11-UTP labelled probes)

It is noted that the recitation of 'set' has been given no weight as the claims recite that the set can contain only 1 nucleic acid molecule.

10. Claims 11, 31, 35, 39, and 43 rejected under 35 U.S.C. 102(e) as being anticipated by Goldgaber et al (US Patent 5,744,368 102(e) date: 11/4/1993).

It is noted that the intended use for the claims carries no patentable weight. The claims recite the limitation "complementary strand", however it is unclear if the claims are drawn to the full complement of one of the sequences of SEQ ID NOS 1-10 or if only a certain degree of homology or complementarity must be present in the sequences, therefore, the claims have been interpreted to encompass sequences which only have a certain degree of complementarity to the claimed SEQ ID NOS. Goldgaber et al teach a sequence (positions 6-15 of SEQ ID NO 3 of Goldgaber) which is complementary to SEQ ID NO 2 (positions 10-19) of the present invention (sequence alignment provided).

It is noted that the recitation of 'set' has been given no weight as the claims recite that the set can contain only 1 nucleic acid molecule.

11. Claims 7, 10-12, 22, and 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by DeBeenhouwer et al., WO9533851 (12/14/1995).

It is noted that the intended use for the claims carries no patentable weight. DeBeenhouwer teaches (p. 40) a sequence of 23 nucleotides (SEQ ID NO 59, positions 5-15) which is identical to nucleotides 1-11 of instantly claimed SEQ ID NOS 1 and 2. Therefore, DeBeenhouwer teaches a sequence that comprises at least 10 contiguous sequences of SEQ ID NOS 1 or 2. The sequence taught by DeBeenhouwer is single stranded and is present as DNA.

It is noted that the recitation of 'set' has been given no weight as the claims recite that the set can contain only 1 nucleic acid molecule.

12. Claims 7, 10-12, 22, and 28-35 rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Draper (US Patent 5,622,854, 102(a) date: 4/22/1997; 102(e) date: 5/14/1992).

It is noted that the intended use for the claims carries no patentable weight. Draper teaches a sequence of 23 nucleotides (SEQ ID NO 22) which at positions 7-16 is identical to positions 2-11 of SEQ ID NO 4 of the instant invention. Therefore, Draper teaches a sequence that comprises at least 10 contiguous sequences of SEQ ID NO 4. The sequence taught by DeBeenhouwer is single stranded and is present as RNA.

It is noted that the recitation of 'set' has been given no weight as the claims recite that the set can contain only 1 nucleic acid molecule.

Claim Rejections - 35 USC § 103

13. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBeenhouwer et al.

It is noted that the intended use for the claims carries no patentable weight. DeBeenhouwer teaches (p. 40) probe with a sequence of 23 nucleotides (SEQ ID NO 59, positions 5-15) which is identical to nucleotides 1-11 of instantly claimed SEQ ID NOS 1 and 2. Therefore, DeBeenhouwer teaches a sequence that comprises at least 10 contiguous sequences of SEQ ID NOS 1 or 2. The sequence taught by DeBeenhouwer is single stranded and is present as DNA. DeBeenhouwer does not specifically teach that the probes are labeled however,

DeBeenhouwer teaches that the probes can be labeled (p. 7), therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to label the probes of DeBeenhouwer to facilitate the detection of hybridization of the probes to a target.

It is noted that the recitation of 'set' has been given no weight as the claims recite that the set can contain only 1 nucleic acid molecule.

Conclusion

14. Claims 16 and 48 are free of the cited prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
1/23/03